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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,304

07/19/2006

John P. Morseman

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9086

70960

7590

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EXAMINER

KIM, JENNIFER M

ART UNIT

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1628

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/597,304	<b>Applicant(s)</b> MORSEMAN ET AL.	
	<b>Examiner</b> JENNIFER M. KIM	<b>Art Unit</b> 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-123 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-123 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-32, 36-53, 80-84, 86, 87, 99, 100 and 112-123 drawn to a method to treat a Reelin deficiency or dysfunction, comprising administering to a patient diagnosed with or suspected of having a Reelin deficiency or dysfunction an amount of a polyunsaturated fatty acid (PUFA) selected from the group consisting of an omega-3 PUFA and an omega-6 PUFA, or a precursor or source thereof with the steps set forth in claim 36.

Group II, claim(s) 33, 34, 86, 87, 99 and 100, drawn to a method of modulating Reelin expression in tissues or fluids, comprising administering to a patient an amount of a polyunsaturated fatty acid (PUFA) selected from the group consisting of an omega-3 PUFA and an omega-6 PUFA, or a precursor or source thereof, effective to modulate Reelin expression in a tissue or fluid of the patient.

Group III, claim(s) 35, 86, 87, 99 and 100 drawn to a method to prevent, reduce or delay the onset of retinal developmental defects or disorder, comprising administering to a patient an amount of a polyunsaturated fatty acid (PUFA) selected from the group consisting of an omega-3 PUFA and an omega-6 PUFA, or a precursor or source thereof, effective to modulate Reelin expression in a tissue or fluid of the patient.

Group IV, claim(s) 54-57, 86, 87, 99 and 100, drawn to a method to monitor the levels of DHA in the brain of a patient, comprising measuring the levels of Reelin expression or biological activity in a biological sample from the patient and estimating the levels of DHA in the brain of the patient based on the measurement of Reelin.

Art Unit: 1628

Group V, claim(s) 59, 60, 86, 87, 99 and 100 drawn to a method to predict the efficacy of incorporation of HUFA into the phospholipid membranes in a patient comprising the steps set forth in claim 59.

Group VI, claim(s) 61-71 86, 87, 99 and 100 -103, drawn to a method to diagnose a DHA deficiency in a patient, comprising steps set forth in claim 61.

Group VII, claim(s) 72-79, 86, 87, 99, 100 and 104 drawn to a method to supplement PUFA in a female during pregnancy and lactation comprising steps set forth in claims 72 and 79.

Group VIII, claim(s) 85, 86, 87, 99 and 100, drawn to a method to prevent, delay the onset of, or reduce a symptom of Alzheimer's disease associated with low molecular weight Reelin phenotypes, comprising the steps set forth in claim 85.

Group IX, claim(s) 86, 87, 88-90, 99 and 100 drawn to a method to improve neuronal migration in a patient, comprising administering to a patient an amount of a poly unsaturated fatty acid (PUFA) selected from the group consisting of an omega-3 PUFA and an omega-6 PUFA, or a precursor or source thereof, effective to modulate Reelin expression in a tissue or fluid of the patient.

Group X, claim(s) 86, 87, 91, 92, 99 and 100, drawn to a method to identify neural progenitor cells, comprising detecting Reelin expression or biological activity in a population of cells, wherein a defined level of Reelin expression or biological activity is associated with neural progenitor cells.

Group XI, claim(s) 86, 87, 93, 94, 99 and 100, drawn to a method to monitor neural development comprising the steps set forth in claim 93.

Group XII, claim(s) 86, 87 and 95-100, drawn to a method to treat or prevent a disorder associated with a deficiency or dysfunction in fatty acid binding proteins, comprising the steps set forth in claim 95.

Group XIII, claim(s) 86, 87, 99, 100 and 105-108, drawn to a method to diagnose a fetal neurodevelopmental disorder, comprising the steps set forth in claim 105.

Group XIV, claim(s) 109-111, drawn to a nutritional supplement or oral pharmaceutical, comprising an amount of Reelin sufficient to delay or prevent the development of a Reelin-deficiency or dysfunction or a disease condition related thereto.

Art Unit: 1628

The inventions listed as Groups I-XIII and Group XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: they lack the same or corresponding special technical features because Group I-XIII utilize unsaturated fatty acid (PUFA) selected from the group consisting of an omega-3 PUFA and an omega-6 PUFA, or a precursor or source thereof while Group XIV utilize the Reelin protein.

The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: they lack the same or corresponding special technical features because each of the groups I-XIII lack the special technical features due to unrelated operation and effect since they are drawn to unrelated disorder with different diagnostic process, for examples method monitor neuro-development is completely different than the supplementing PUFA to female during pregnancy.

If Applicant elects Group I, following election of species is required:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A) various subjects to be treated (e.g. Down's Syndrome, cystic fibrosis, etc.. see claim 30).

B) Various PUFA agents (ARA, EPA, DHA, etc. see claims 113, 117).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Art Unit: 1628

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 30 for example correspond to various subject having different medical disorder to be treated.

Claims 113 and 117 for example correspond to various active agents to be employed.

The following claim(s) are generic: 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the medical disorders have different etiology and different known treatment; each of the active agents have different physical/chemical properties.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Art Unit: 1628

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### **Communications**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1628

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/  
Primary Examiner, Art Unit 1628

Jmk  
March 25, 2010